EXHIBIT M

WORK INSTRUCTION FOR NEW PRODUCT DESIGN CONTROL

PR800-011
Version 4
APPENDIX I - V

Version	Summary of Change	Form Changed?
4	Update procedure to include clarification of user needs, design outputs, design reviews, and design changes. Updated Appendix II to reflect clarifications. Additional references included. (CP2002GXJ001)	Yes

*"Capitalized product names are trademarks of ETHICON" *(Refer to the rules of proper trademark usage located on the ETHICON Intranet.)*

** Changes
/// Deletions

SCOPE:

- This procedure applies to the development of new products. See PR800-012, Work Instructions for Design Changes to Existing Products, if you are making a change to an existing product.
- This procedure applies to all Business Units governed by Ethicon Quality Systems.
- Components provided by Ethicon to another company for their device are governed by either the other company's Design Control System or this procedure, as agreed upon between the two companies.
- The development of new products designed/developed by an external company wherein their Design Control System is deemed appropriate by an Ethicon approved assessment is governed by the other company's Design Control System. In all other cases the development is governed by this document.

- This procedure does not apply to Class I devices except for the following:

    1) When required by any market (country) in which the device is going to be released.
    2) Devices noted in Sec. 820.30 of 21 CFR Part 820.
    3) All Class I exempt devices must have documentation of functionality, Biocompatibility, sterility, stability, and risk analysis at a minimum and must be effectively transferred to production.

OVERVIEW

This document describes the Design Control Process, which begins once a Project Leader has been assigned, Project Team has been assembled, and the project enters Feasibility. (The project has been approved into the Pipeline. The idea or initiative is officially recognized as a project and will be given the support and resources needed to fulfill the NPD requirements.)

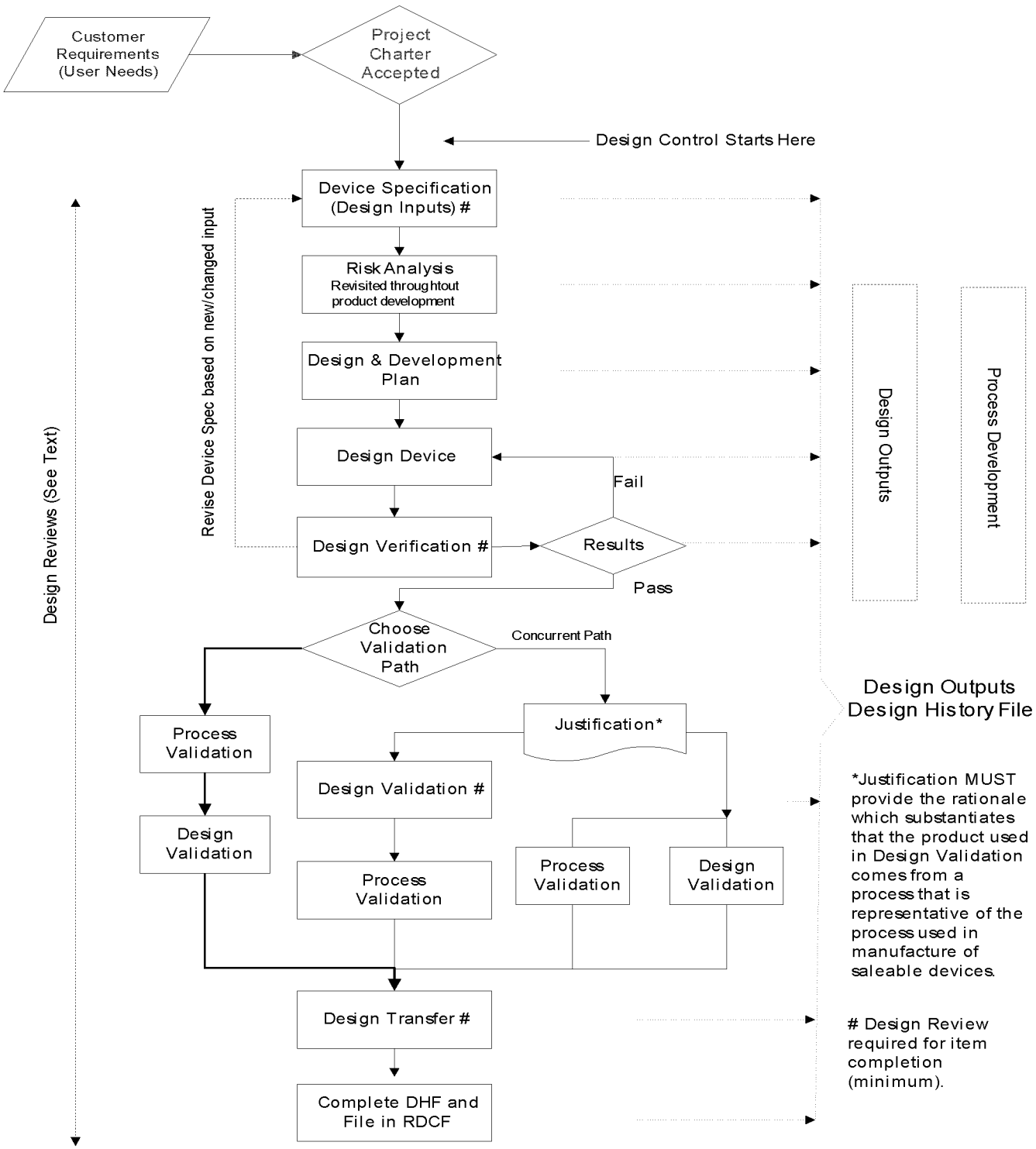
The Worldwide Vice President of Research and Development is the owner of the Design Control Process.

This document describes the following activities:

- Obtaining User Needs (Including Intended Use)
- Creating Product Description
- Creating Device Specification (Design Inputs)
- Performing Risk Analysis
- Creating the Design & Developing Plan (D&D Plan)
- Creating Design Outputs
- Performing Design Verification (Design Outputs Vs Design Inputs)
- Performing Process Development & Validation
- Performing Design Validation
- Performing Design Transfer (Design Outputs are finalized)
- Conducting Design Reviews
- Assembling and Completing a Design History File

///

** **Flowchart of New Product Design Control Process**



IMPORTANT: All <u>required</u> documentation and all revisions to such must be filed in DHF.

Obtaining User Needs (Including Intended Use)

	Activity	Responsibility
	1. Obtain user needs/intended use via appropriate methodology for Voice of the Customer.	Marketing in collaboration with R&D (include other functions as needed)
**	2. Sources of information may include but are not limited to customer feedback, customer complaints, market research, customer visits, surveys, focus, groups, etc.	Marketing & Project Team
	3. Document and file user needs/intended use and source of information (including Who, What, When, How obtained & by Whom). (File in Marketing in a retrievable fashion)	Marketing

Creating the Product Description

Activity	Responsibility
1. Complete Product Summary section of Product Description on Appendix 1. **IMPORTANT**: • It is not required that all customer requirements or device specifications be determined prior to issuing the initial Version. • For devices with computer systems refer to OP603-276 for CSV deliverables.	Marketing
2. Complete User needs/Intended use and Source on Appendix II.	Marketing
3. Identify and document the methodology to resolve all ambiguous and conflicting user needs/intended use.	Project Team
4. Resolve all issues.	Project Team

Creating the Product Description

Activity	Responsibility
5. Document resolution and attach to Appendix II.	Marketing
** 6. Obtain approval on Product Description from Product Director & Business Unit R&D Vice President.	Project Leader
7. Forward all documentation to Project Leader.	Marketing
8. File all documentation in DHF.	Project Leader
9. Update and Review the Product Description when appropriate to document changes.	Project Leader

IMPORTANT: Anytime there is a change to the user needs/intended use, the impact to the Product Description Document and Device Specification must be addressed. Also, with any change to the Device Specification, the impact to the user needs/intended use must be addressed.

Creating Device Specification (Design Input)

Activity	Responsibility
1. Translate Product Description into measurable technical characteristics. **ATTENTION:** This includes labeling & packaging.	R&D in collaboration with Marketing (include other functions as needed)
2. Complete Device Specification documentation on Appendix II.	Project Team
3. Perform Design Review.	Project Team
** 4. Gain approval on Device Specification from Business Unit R&D Vice President and Group Product Director.	Project Leader
5. File all documentation in DHF.	Project Leader

Creating Device Specification (Design Input)

Activity	Responsibility
6. Update and Review Device Specification when appropriate to document changes to the Device specification. (Any changes to the Device specification must be approved as stated above.) **IMPORTANT**: Ensure that user needs/intended use is not impacted.	Project Leader

IMPORTANT: Anytime there is a change to the user needs/intended use the impact to the Product Description Document and Device Specification must be addressed. Also, any change to the Device Specification the impact to the intended need of the user must be addressed.

Performing Risk Analysis

Activity	Responsibility
1. Assign Risk Analysis Leader to perform Risk Analysis.	Project Leader
2. Perform and document Risk Analysis per PR602-003 & OP650-010. **IMPORTANT**: Critical Quality Parameters should be identified via these procedures.	QAE
3. Evaluate Risk Analysis.	QAE
4. Determine the next steps.	Project Leader
5. Address and document actions and the closure of issues.	QAE
6. File Risk Analysis and each revision in the Design History File.	Project Leader

IMPORTANT: Risk Analysis should be performed at various stages throughout product development. When design changes are made risk analysis should be performed to ensure that impact of the changes are assessed.

Creating Design & Development Plan

Activity	Responsibility
1. Develop an overall development strategy and communicate it to the team members.	Project Leader
2. Assign and document the team member who is functionally responsible for preparation of each section of the D&D Plan per Appendix III.	Project Leader
3. Develop & document strategy(s)/plan(s) for assigned section(s) of the D&D Plan. (Include departments and/or functions interfacing to complete this plan.)	Assigned Team Member
4. Forward documentation to the Project Leader and appropriate management.	Assigned Team Member
5. Compile strategy(s)/plans into the D&D Plan per Appendix III (after completion of Version 1 of the Device Specification).	Project Leader
6. Review D&D Plan with Project Team.	Project Leader
7. Obtain approval on D&D Plan from R&D Vice President for Business Unit.	Project Leader
8. File D&D Plan in DHF.	Project Leader
9. Execute the D&D Plan.	Project Team
10. Update, Review & Approve the D&D Plan and impact to Risk Analysis when appropriate and document changes as they occur.	Project Leader

**

**

Important: D&D plan should include rationale for choosing the validation path (See flow chart on page 3 of this document).

Creating Design Outputs

Activity	Responsibility
1. Create Design Outputs per all approved controlled procedures throughout the Design	Project Team Members

Creating Design Outputs

	Activity	Responsibility
	and Development process. (e.g., raw material specifications, finished goods specifications, technical drawings, labeling and packaging specifications including IFUs) **IMPORTANT**: Any changes to these must be controlled through the change mechanism for the procedure and/or output required.	
**	2. Ensure all appropriate essential Design Outputs are identified	Project Leader
	3. Ensure Design Output documents are approved prior to Design Transfer	Project Leader

** Documenting Design Changes During Development

Activity	Responsibility
1. During development of the device, changes may occur in order for the device to conform to documented Design Inputs (Device Specifications). Such changes shall be documented and filed in the DHF. **ATTENTION:** When changes are made to Appendix II (i.e., Device Specification, User Needs, etc.), all subsequent Design Control activities (reference the "Flowchart of New Product Design Control Process") shall be revisited to determine impact and potential need to repeat or revise affected items.	Project Team
2. File design change documentation in the DHF.	Project Leader

ATTENTION: Changes to the Appendix II require approvals. Refer to PR573-014, Work Instructions Governing Ethicon Change Control Procedures, for procedures needing to be considered when making changes.

Performing Design Verification

Activity	Responsibility
1. Write the appropriate number of protocols to ensure each requirement in the Device Specification has been met by the design[++]. **ATTENTION**: This includes labeling and packaging requirements.	R&D Team Member (s)
2. Obtain approvals for the protocols by QAE at minimum. (other functional groups as appropriate)	R&D Team Member (s)
3. Ensure that appropriate test methods have been validated per PR800-002.	QAE Team member
4. Conduct the testing per the protocols.	R&D or appropriate functional department
5. Document the results of each test and forward all documentation to the Project Leader.	R&D Team Member (s)
6. Investigate root cause and determine appropriate solution if this verification does not indicate that the design meets all requirements in the Device Specification. Document and file in DHF. Repeat Design Control steps as necessary.	Project Team
7. Update Appendix II in the Design Verification Column with the location and identifier for the Results for each requirement.	Project Leader
8. Perform Design Review.	Project Team
9. File appropriate documentation in the DHF.	Project Leader

** [++] **IMPORTANT: Design verifications can occur throughout the design development process. The final design verifications must be conducted as indicated above.**

Performing Process Development &Validation

Activity	Responsibility
1. Perform Process Development & Validation(s) per PR161-001, Work Instructions for Equipment and Process Control Procedure.	Project Leader & Team

Performing Design Validation

Activity	Responsibility
1. Develop Design Validation Strategy. **IMPORTANT**: The Design Validation Strategy must include actual/simulated use testing for all intended indicated uses, packaging, labeling, etc.	Project Leader & Team (ensure Marketing and Medical Affairs participation)
2. Gain approval of the strategy from the Director of Medical Affairs.	Project Leader
3. Generate a protocol which reflects the strategy.	Assigned Team Member
4. Review the Design Validation Protocol at a formal Design Review prior to conducting the Design Validation **IMPORTANT**: • A Medical Affairs person must be in attendance for this part of the Design Review if the Validation includes cadaveric or human clinical trials. • Corporate Product Characterization (CPC) must be in attendance if animal trials will be included.	Project Leader
5. Gain approval on the protocol from QAE,	Project Leader

Performing Design Validation

Regulatory and Marketing team members. **IMPORTANT:** a) Medical Director must approve if human clinical trials are used. b) CPC must approve if internal animal studies are supporting this validation.	
6. Schedule the Studies.	Marketing
7. Conduct the Studies.	Marketing, Medical Affairs, CPC, and R&D
8. Document the results.	Appropriate Functional Department
9. Write Completion Report and forward appropriate documentation to Project Leader.	Appropriate Functional Department
10. Perform formal Design Review.	Project Team
11. • Investigate root cause. • Determine appropriate solution if this validation does not indicate that the design meets all the requirements in the Device Specification and user needs/intended use. • Document and file in DHF. • Repeat Design Control steps as necessary. Ensure that the device specification meets the user needs/intended use.	Project Leader
12. Update Appendix II in the Design Validation Column with the location and identifier for the results for each requirement.	Project Leader
13. File appropriate documentation in the DHF.	Project Leader

IMPORTANT: Design Validation occurs after Design Verification. When conducting Design Validation studies, <u>coaching</u> of users is not included.

Performing Design Transfer

Activity	Responsible
1. Schedule a design review after successful completion of Process and Design Validations.	Project Leader
2. Conduct the design review.	Design Review Team
3. Confirm the completion of all the items on the Design Transfer Checklist (Appendix IV). **IMPORTANT:** Ensure all applicable protocols used in the validation of the product are made obsolete in the DMS System.	Design Review Team
4. During the design review, fill out and approve Design Transfer Checklist (Appendix IV).	Project Leader and Designated Approvers
5. File Design Transfer Checklist (Appendix IV) documentation in Design History File.	Project Leader

IMPORTANT: A representative from each manufacturing location must be included to review the applicable manufacturing operations that are performed at that location.

Conducting Design Review(s)

Activity	Responsibility
1. Schedule a Design Review consistent with the D&D plan. **IMPORTANT:** Additional Design Reviews can be conducted as needed.	Project Leader

Conducting Design Review(s)

	Activity	Responsibility
	2. Determine discussion topics, discussion leaders, and participants. **IMPORTANT**: At minimum, it must include: - Project Leader, - Appropriate Project Team Members, - Specialist personnel as required, - Designated facilitator, - Designated minute recorder, and - Independent Observer(s) i.e., someone who does not have direct responsibility for design stage being reviewed.	Project Team
	3. Determine the documentation required to be reviewed and identify the person(s) responsible for providing that documentation. **IMPORTANT**: This documentation should be distributed prior to the meeting with adequate time for review.)	Project Leader
	4. Publish the schedule and agenda.	Project Leader
	5. Conduct the Meeting.	Facilitator
**	6. Evaluate all Design Outputs including the design; identify issues, potential problems, resource issues or gaps, Design Control activities, adherence to the D&D plan and gain agreement on future actions. Ensure that all appropriate essential Design Outputs have been identified.	Project Team & Independent Observer(s)
	7. Document the decisions, action items and person responsible for closing the item.	Minute Recorder
**	8. The Project Leader must communicate all action items resulting from the Design Review to appropriate Management Personnel.	Project Leader
	9. Determine and document in the minutes the manner in which the Independent Observer	Independent Observer(s) & Project Team

Conducting Design Review(s)

Activity	Responsibility
will review the results from each action item.	
10. Complete & publish the meeting minutes.	Minute Recorder
11. File a copy of the meeting minutes in the DHF.	Project Leader

Assembling & Completing a Design History File

Activity	Responsibility
1. Prepare a binder for the DHF; label for the project and include the Design History File Template.(Appendix V)	Project Leader
2. Determine the contents of the DHF considering the DHF Template in Appendix V.	Project Team
3. As each identified item is completed or supporting documentation is received, place the documentation into the DHF.	Project Leader
4. Compile the contents into an organized fashion along with a table of contents. (Note: originals or copies of documents are acceptable.).	Project Leader
5. Transfer contents into Acco Binder preparing for archiving in RDCF.	Project Leader
6. Review and verify contents for appropriateness, completeness, and required approvals. .	Project Leader
7. Ensure all action items from Design Reviews have been closed and documented.	Project Leader
8. Sign and date the DHF Template (Appendix V) when DHF is complete.	Project Leader

Assembling & Completing a Design History File

Activity	Responsibility
9. Verify the DHF for completeness.	QA or RA Team Member
10. Sign and date the DHF Template (Appendix V).	QA or RA Team member
11. File DHF in RDCF.	Project Leader
12. Prepare and forward receipt of DHF to Project Leader.	RDCF Coordinator
13. Receive Receipt.	Project Leader

IMPORTANT: After a Device Specification has been initiated and as you develop and test your design any change to your design should be documented and filed in the DHF.

APPENDICES

APPENDIX	TITLE
Appendix I	Product Description Document
Appendix II	Relationship between User Needs/Intended Use, Device Specification, Design Verification, Process Control, Design Validation
Appendix III	Design & Development Plan
Appendix IV	Design Transfer Review Checklist
Appendix V	Design History File Template

All appendices are controlled forms and are detached from the body of this document.

REFERENCES

	DOCUMENT #	DOCUMENT TITLE
	PR120-004	Work Instructions for Ethicon Inc's External Manufacturers
	PR573-014	Work Instruction Governing Ethicon Change Control Procedures
	PR800-002	Company Procedure for Test Method Validation
	PR800-012	Work Instruction for Design Changes to Existing Products
	PR602-003	Company Procedure for Design Risk Management
	PR161-001	Work Instructions for Equipment and Process Control Procedure
	OP603-276	Work Instructions for the Design and Development of Computer Systems
	OP650-010	Operating Procedure for Design Safety Assessment
**	21 CFR Part 820	Quality System Regulation
**	ISO 13485	Quality systems – Medical devices – System requirements for regulatory purposes